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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,522	05/02/2005	Istvan Hudak	9007-1011	1625

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,522

Applicant(s)

HUDAK, ISTVAN

Examiner

James W. Rogers, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 09/14/2007 have been entered. Any rejection from the previous office action filed 06/14/2007 not addressed below has been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36,40-41,43,45-50,54-55 and 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Garibaldi (US 6,296,604 B1, cited in last office action).

Garibaldi teaches a biocompatible composition comprised of a precipitating polymer such as polyurethane, an adhesive and a magnetic embolic agent (including barium or tantalum), the polyurethane was dissolved in a biocompatible solvent such as

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DMSO and EtOH. See col 2 lin 63-col 3 lin 7, lin 53-62, col 4 lin 13-23 and claims 1-9 and 14. Regarding the limitation that the composition is used to fill or short-circuit a vascular cavity, Garibaldi teaches several uses for the composition to treat vascular defects including covering aneurisms and covering injured sections on the inside of a vessel, thus meeting the limitation of filling a vascular cavity. See col 8 lin 10-54.

Regarding the limitations on the viscosity of the composition Garibaldi claims a viscosity between about 30 and about 1500 centipoise within applicants specified range, the examiner assumes the viscosity measurements would be conducted at room temperature. Regarding claim 58 Garibaldi specifically mentions that the compositions are delivered by catheter.

Response to Arguments

Applicant's arguments filed 09/14/2007 have been fully considered but they are not persuasive.

Applicants assert that their transitional phrase "consists essentially of" precludes the magnetic materials of Garibaldi which applicant's purports is different then their claimed auxiliaries which are paramagnetic. Also applicants state that the adhesives used in Garibaldi are now excluded because the adhesives would change the materialistic properties of the composition.

The relevance of these assertions is unclear. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. Firstly the metal powder added to the compositions of Garibaldi are

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Paramagnetic, therefore by applicants own admission paramagnetic particles aren't excluded by applicants new transitional phrase. Additionally Garabaldi teaches that the metal powder can be tantalum or barium, two elements that are claimed as auxiliaries in applicant's claim 43. Regarding the assertion by applicants that the adhesive would change the materialistic properties of the composition, Garabaldi clearly recites that the appropriate composition properties are maintained when the adhesive is no more than 50% of the total weight of the adhesive and polymer. See col 12 lin 54-58. Thus from this recitation it is clear that the adhesives of Garibaldi do not materially affect the compositions properties if used in lower concentrations, the most preferred ratio of adhesive to polymer is 1:6.7.

Claims 32-34,37-42,44,46-48 and 51-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Marinovic (EP 0 280,451, cited in last action).

Marinovic teaches polyurethanes prepared by mixing prepolymers of diisocyanate (including MDI) and polyols such as polypropylene glycol, the polyurethanes were useful as space filling adhesive sealants in surgery. See abstract, page 3 lin 14-58, page 4 lin 6-58 and page 6 lin 11-36. Regarding claims 32 and 46 the intended use of the composition for filling or short circuiting vascular cavities was given no patentable weight by the examiner because the claims are drawn to a method of preparing a composition or a kit or the claims are drawn to a composition or a kit.

"Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81. The

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polyurethanes within Marinovic could be used in a package containing separate compartments for the polymer and an aqueous solution containing a chain extender (meets limitation of usual auxiliary and solvent), the polymer and aqueous solution are conveniently mixed prior to use as space filling tissue adhesives. See claims 12-16. Regarding the limitations regarding MW of the polyurethane, Marinovac teaches that the polyglycol has an average MW of 650-5000 and the diisocyanate/polyglycol monomers are in a 2:1 ratio, therefore the MW of the entire polymer would be between 1,950-15,000, within applicants specified range. Regarding the limitation that the diol component is HO-R'-OH, where R' stands for a C1-C8 alkylene group, polypropylene glycol is formed by a condensation of the C3 diol propylene glycol, as evidenced by applicants own specification polypropylene glycol is a special sub-group of diols and therefore meets applicants limitation above. See [0072] in US 2006/0008499 A1 patent application publication of 10/533,522.

Response to Arguments

Applicant's arguments filed 09/14/2007 have been fully considered but they are not persuasive.

Applicants assert that Marinovic does not teach polyurethanes but rather he teaches polyETHERurethane urea polymers. Applicants further assert that the prepolymer of Marinovic precipitates only after it reacts with a chain extender and not from separation from a solvent. Lastly applicants assert that the polyetherurethane urea polymers are adhesives and would therefore stick to the blood vessel wall.

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The relevance of this assertion is unclear. The polymer shown on page 6 lin 5-8 would meet the limitation of a polyurethane. The polymer contains 2 urethane monomeric units in its structure -NHCOO-(polyether)-OCONH-, a polyurethane is any polymer consisting of a chain or organic units joined by urethane links. While the polymer also contains repeat units of urea this is not excluded from applicants claimed invention. Regarding the last two assertions by applicants on how the polymer precipitates and that the polymer would stick to the vessel wall, applicants claimed invention as currently amended is a **method of preparing a composition**, not a method of short-circuiting a vascular cavity. Therefore in order to meet applicants claimed invention only the steps of making the composition and the ingredients of that composition must be met. Marinovic teaches adding all of the ingredients in applicants claims rejected above, therefore Marinovic anticipates applicants claimed invention. The recitation of short-circuiting a vascular cavity, the polyurethane solidifies upon separation from solvent and the components do not stick to vessel walls are all forms of intended use type of limitations for the composition. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

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- (A) statements of intended use or field of use,
- (B) "adapted to" or "adapted for" clauses,
- (C) "wherein" clauses, or
- (D) "whereby" clauses

Also since the polymers are delivered to the site with solvent and chain extender it would be inherent that the solvent would evaporate just as in applicants claims and at least hasten the precipitation process.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-37,39,43-51,53 and 56-58 rejected under 35 U.S.C. 102(e) as being anticipated by Porter (US 2002/0165583 A1).

Porter teaches a composition for embolization of a vascular site in a blood vessel. See abstract and [0016]. The composition comprises a prepolymer that forms a polyurethane in situ when delivered to the vascular site, the polyurethane is formed from a polyether polyol (polyoxyethylene, polyoxypropylene and the like) and an isocyanate including 4,4-diphenylmethanediisocyanate. See [0050],[0059]-[0061]. In one embodiment of Porter the polymer is dissolved in a solvent including ethanol. See

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[0059]. Porter states that in order to precipitate the polymer faster a flush stream can be used to accelerate the diffusion of solvent. See [0087]-[0088]. The compositions could further comprise a radio-opaque agent including iodinated oils, tantalum, tungsten and salts such as barium sulfate. See [0067]. Regarding claim 58 Porter specifically mentions that the compositions are delivered by catheter. See figures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi (US 6,296,604 B1) in view of Marinovic (EP 0 280,451).

Garibaldi is disclosed above. While Garibaldi discloses the use of polyurethanes the patent does not detail the exact diisocyanate and polyol monomers that were used to produce the polymer and the patent is silent on the MW of the polyurethanes.

Marinovic is disclosed above.

Marinovic is used to primarily show that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as currently claimed by applicant was already known to be used as an adhesive sealant in surgery. The advantages of the disclosed adhesives within Marinovic is its

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application as a viscous liquid which can be sculpted, once in place the adhesive is rubbery and not brittle or subject to shattering and the adhesive is non-toxic.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Garibaldi discloses all of applicants claimed invention but is silent on the monomers used to produce the polymer and the polymers molecular weight while Marinovic discloses that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as claimed was already known to be used as an adhesive sealant in surgery. The motivation to combine the above documents would be to produce a composition comprised of a polyurethane an auxiliary and solvent useful for filling vascular cavities. The advantage of the disclosed composition with a polyurethane within a specific MW and produced by the condensation of specific monomers such as MDI and C1-C8 diols would be that the polyurethane would have a desirable viscosity which is rubbery when applied and not brittle and is non-toxic all of which are obviously desirable traits in surgical adhesives. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 09/14/2007 have been fully considered but they are not persuasive.

Applicants essentially have incorporated the same arguments from Garibaldi and Marinovic above, ie Garibaldi discloses adhesives and magnetic particles that are now

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excluded and Marinovic does not disclose 1) polyureathanes, 2) polyurethane that solidifies upon separation from solvent and 3) the components would stick to blood vessel walls. Therefore applicants surmise that the combination does not teach all of the claimed elements of their invention.

The remarks by the examiner for Garbaldi and Marinovic are incorporated herein in that Garabaldi's adhesives and magnetic particles are not excluded and Marinovic does disclose polyurethanes. The intended use limitations as detailed above were given no patentable weight by the examiner.

Claims 32-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 2002/0165583 A1).

Porter is disclosed above. Porter while stating that the polyol portion of the polyurethane has a MW in the range of 250-2900 is silent on the total weight of the entire polyurethane. However it would have been obvious to one of ordinary skill in the art to vary the concentrations diisocyanate and the reaction conditions to form a polyurethane mixture with a polydispersity index that achieves the desired properties. Regarding claim 52, it also would be obvious from the disclosure of Porter that the main diol component would comprise a very high concentration of polyether. This is because the polyurethane made by Porter would contain mostly polyether polyol, which has a much higher molecular weight than the diisocyanates that form the polyurethane linkers. The polymer can further comprise 1 to 50% of another polymer including hydroxyl or amine terminated compounds, further allowing one with skill in the art to adjust the

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amount of polyol in the backbone. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In *re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In *re* Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). Regarding the limitations on the viscosity of the composition, since the composition of Porter is obviously the same in scope to applicants claimed invention it is obvious that the viscosity of the composition will be the same.

Claims 32-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi (US 6,296,604 B1) in view of Porter (US 2002/0165583 A1).

Garibaldi is disclosed above. While Garibaldi discloses the use of polyurethanes the patent does not detail the exact diisocyanate and polyol monomers that were used to produce the polymer and the patent is silent on the MW of the polyurethanes.

Porter is disclosed above.

Porter is used to primarily show that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as currently claimed by applicant were already known in the art at the time of applicants claimed invention to be used in embolic compositions. ,

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Thus the claimed invention would have been *prima facie* obvious because the substitution of one known element such as polyurethanes disclosed within Garibaldi for another known element such as the polyurethanes disclosed within Porter would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER